Accuracy Evaluation of the FDA-Cleared BabySat™ Pulse Oximeter in a Home-Monitoring Study

Results from a home-monitoring clinical study evaluating oxygen saturation and pulse rate accuracy of the Owlet BabySat monitoring system in infants

Owlet Baby Care, Inc., Lehi, UT

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Introduction

Oxygen saturation is a crucial measure of how much hemoglobin is currently bound to oxygen compared to how much hemoglobin remains unbound, thereby revealing important information on lung and heart functionality. Pulse oximetry is a painless, noninvasive method of measuring the percentage of hemoglobin in the blood that is saturated with oxygen. Since its introduction in the 1980s, pulse oximetry has revolutionized the medical field and has now become a part of the expanded vital signs evaluation of newborns. **Screening with pulse oximetry can not only provide early diagnosis of infants with critical congenital heart defect (CCHDs) but may also identify many other conditions which may present with hypoxemia such as infections, lung disease, hemoglobinopathy, or persistent pulmonary hypertension.** Many of these conditions are initially asymptomatic, leading to patient discharge before a diagnosis can be made. This can severely delay treatment, leading to worse outcomes or increased neonatal mortality.[1] Delayed diagnosis of neonatal hypoxemia can cause adverse life-long consequences such as weakened cardiac function, low blood pressure, and neurodevelopmental impairment in humans. Therefore, in 2011 pulse oximetry was added as a recommended infant screening tool by the American Academy of Pediatrics and the American Heart Association, and within a few years all 50 states plus the District of Columbia had implemented this in their standard screening protocol for indirect detection of clinical and subclinical levels of hypoxemia which can be related to many cardiopulmonary pathologies. Knowing the importance of monitoring saturated oxygen levels in vulnerable infants, clinicians often prescribe at-home pulse oximetry monitoring. Several studies have reported the importance of at-home pulse oximetric monitoring of infants at risk and thereby prevented potential long term adverse consequences.[2,3] In 10-year outcomes from a home monitoring study of interstage patients with Norwood stage 1 palliation (S1P) carried out by Rudd et al., at-home monitoring of oxygen saturation and weight resulted in 98% survival as opposed to 10-20% mortality associated with unmonitored routine care during the interstage period. Most importantly, authors reported that more than half of discharged patients had timely detection of oxygen desaturation or concerning weight changes prompting hospital readmission. Most of these readmitted infants had diagnoses associated with interstage death in previous unmonitored reports, clearly demonstrating the importance of at-home monitoring of vulnerable cases.[1] Several crucial decisions are dependent on the accuracy of pulse oximetry, such as early screening of CCHD, neonatal resuscitation and ventilator support, continual home monitoring of oxygen levels, precise screening and monitoring of other conditions which may present with hypoxemia such as infections, lung disease, hemoglobinopathy, and non-critical CHD. **Given the criticality of pulse oximetry, it is important to understand its operation and its limitations.** Pulse oximetry is based on the principles of differential absorption of red and infra-red light by oxygenated hemoglobin (OHb) and deoxygenated hemoglobin (HHb).[3] The accuracy of a pulse oximeter is evaluated by the difference between SpO2 (the oxygen saturation values reported by the pulse oximeter) and SaO2 (the oxygen saturation of arterial blood measured by co-oximetry, that is considered the gold standard measurement) readings. However, most pulse oximeter validation studies were based on SaO2 measurements in healthy young volunteers over a range of desaturation values (SpO2 70–100 %). Since it is unethical to desaturate volunteers below SaO2 levels of 70–80 %, extrapolation is used to derive lower SpO2 values. It is important to note that the real-world accuracy may differ from the lab settings. FDA-cleared prescription pulse oximeters are required to have a minimum average (mean) accuracy, reported as Accuracy Root Mean Square or A_{rms}, within 3% of arterial blood gas values in order to meet accuracy metrics set by the International Organization for Standardization (ISO). Additionally, several factors are known to influence the accuracy of pulse oximetry readings, such as skin tone, sensor placement, motion, bright light, device calibration, hemoglobin levels, etc.[4,5,6] It is important to factor in these influences while determining the accuracy of the device. Therefore, SpO2 readings should always be considered as an estimate of peripheral oxygen saturation. Despite all these considerations, at-home monitoring has provided parents with a sense of reassurance that the infant's condition is stable and an ability to monitor progress and improvement over time.[3,7] However, these benefits also came at the cost of navigating cumbersome devices and overly sensitive alarms, which often result in heightened stress and anxiety in care givers due to constant false alarms. **Thus, there is a need to revolutionize home based pulse oximetry with an easy to use infant-centric design with hospital grade accuracy while factoring in infant daily motions.**

Problem Statement

Given the importance of continuous monitoring of oxygen saturation by pulse oximetry (SpO2) in susceptible infants, the accuracy of these devices is crucial. However, evaluating the accuracy of pulse oximeters in an at-home setting while factoring in infant motion, skin tone, placement of the sensor, adverse events due to skin contact, which are all known to decrease efficacy of oxygen saturation readings, has been lacking.

BabySat Monitoring System

BabySat is a clinician prescribed pulse oximeter for home use. The BabySat monitoring system includes a Sock, a Sensor, a Base Station and the Owlet Care+ App (the "App"). The Sock secures the Sensor to the baby's foot and the Sensor measures SpO2 and pulse rate (PR) readings and transmits these readings wirelessly through bluetooth technology to the Base Station. The Base Station monitors the baby's readings and alarms if the readings are outside specific limits. The Base Station also relays the data to the App which displays the baby's reading and any alarm activity. This device is intended for patients greater than 1 month old and weighing between 6 and 30lbs.

Figure 1: BabySat

Preclinical Accuracy Testing in a Lab Setting:

In a pre-clinical lab setting accuracy of BabySat vital sign readings is comparable to the gold standard SaO2 Co-Oximetry:

The accuracy testing of the OSS 3.0 sensor, as used in BabySat, in a healthy adult population under laboratory conditions was conducted in 18 subjects across the extremes of skin tone. Arterial blood gas sampling was measured by functional SaO2 co-oximetry across a range of 70-100% SpO2. Accuracy was found to meet the ISO standards for pulse oximetry. In addition, when tested on a simulator device, BabySat consistently reported a pulse rate within 3 bpm of the simulator for pulse rates ranging from 30 bpm to 300 bpm and perfusion indices from 0.1% to 20%.

Table 1: BabySat SpO2 readings are comparable to co-oximetry SpO2 reading

SpO2 Accuracy Analysis Range	Non-motion Study Results	Motion Study Results
70 to 100%	± 2.72% ARMS	± 2.63% ARMS
70 to 80%	± 3.05% ARMS	± 3.11% ARMS
80 to 90%	± 2.67% ARMS	± 2.22% ARMS
90 to 100%	± 2.46% ARMS	± 2.63% ARMS

Objective of 'At-Home' Monitoring Study:

The objective of this study was to demonstrate the accuracy of the BabySat relative to an FDA-cleared pulse oximeter comparator, the Masimo Corporation Rad-97™ Pulse Co-Oximeter®, in measuring pulse rate and oxygen saturation in the intended infant population per indications for use in an at-home setting.

Study Design

A prospective, nonrandomized, single arm study was carried out in an at-home setting to collect real-world evidence in the device's intended use infant population. 35 infants were enrolled and monitored for a 2-hour data collection period. The test device BabySat and the comparator device, the Rad-97 Pulse Co-oximeter, were used on both legs of each enrolled infant. The first co-primary effectiveness endpoint was agreement between BabySat and the comparator device for pulse rate. The second co-primary effectiveness endpoint was agreement between BabySat and the comparator device for oxygen level (SpO2). Agreement for each co-primary endpoint was based on ARMS calculated over all paired measures. In addition, descriptive data regarding infant movement types were recorded and correlated with accelerometry measurements during those behaviors. ARMS for pulse rate and SpO2 were calculated between BabySat and the comparator device to specifically evaluate performance during motion. Safety endpoints include any adverse event that occurs during, or is observed after completion of, the 2-hour use of the test device.

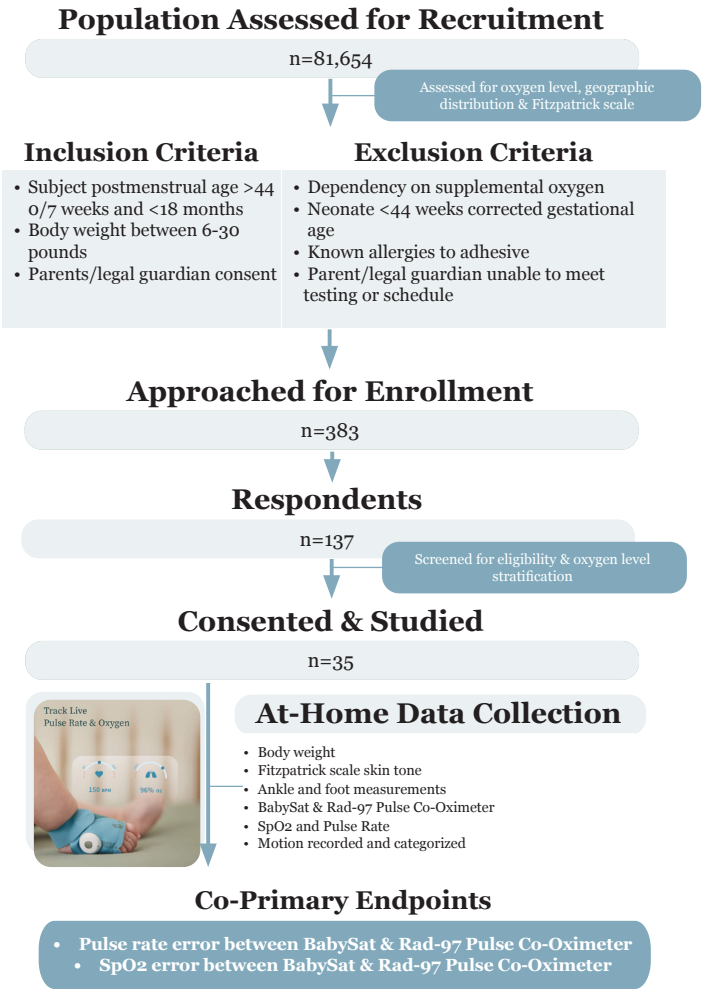


Figure 2: Study Design- 35 subjects were enrolled in a single arm, non-randomized, at home study, to compare the accuracy of BabySat with the FDA-cleared comparator Rad-97 Pulse Co-Oximeter

Study Demographics

Demographic data on all participants included in this study are represented below in Table 2. Measurements including age, sex, weight, foot and ankle circumference, sock size and Fitzpatrick score were recorded. Mean age in months from birth was 8.2 (SD 4.5) with a range from approximately 2 to 18 months. Twenty-five (25) of the 35 subjects (71.4%) were male. Mean weight was 17.2 (SD 4.2) pounds, with a range of 9.5 to 26 pounds. Foot and ankle circumference were similar, both being approximately 12 cm with a standard deviation of 1.7 cm. Most subjects, (28/35, 80%) wore the larger sock size. Fitzpatrick scores were primarily 2 (27/35, 77.1%), with 5 subjects (14.3%) having scores of 5 or 6.

Table 2: Demographics of the participants

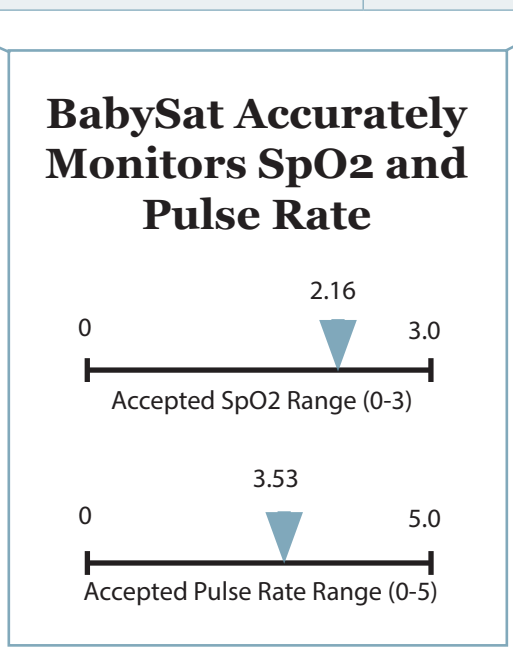
Characteristic	
Study Demographics	
Age (Months)	
Mean (SD)	8.2 (4.5)
Median	8.4
IQR	4.2, 11.0
Range	1.7, 17.7
Age Category	
(00 to 06M)	12 (34.4%)
(06 to 12M)	15 (42.9%)
(12 to 18M)	8 (22.9%)
Sex	
Female	10 (28.6%)
Male	25 (71.4%)
Weight (lb.)	
Mean (SD)	17.2 (4.4)
Median	18.0
IQR	14.0, 20.0
Range	9.5, 26.0
Foot Circumference (cm)	
Mean (SD)	11.9 (1.7)
Median	12.0
IQR	11.0, 13.2
Range	7.5, 14.7
Ankle Circumference (cm)	
Mean (SD)	12.5 (1.7)
Median	12.5
IQR	12.0, 13.5
Range	8.1, 16.0
Sock Size	
1	7 (20.0%)
2	28 (80.0%)
Fitzpatrick Score	
1	2 (5.7%)
2	27 (77.1%)
3	1 (2.9%)
5	2 (5.7%)
6	3 (8.6%)

BabySat vital sign readings are comparable to FDA-cleared Rad-97 Pulse Co-Oximeter

Across the 35 enrolled subjects, BabySat and Rad-97 Pulse Co-Oximeter reported the vital sign data (SpO2 and PR) from the 41.5 hours of simultaneous readings. Root mean square (RMS) error was calculated for each subject using all paired test and comparator data and then averaged across subjects to yield an ARMS. This procedure was used for both SpO2 and for PR. ARMS for SpO2 was below the limit of 3.0 at 2.16 (SD 0.77). ARMS for PR was below the limit of 5.0 at 3.53 (SD 1.31).

Table 3: SpO2 (%) and pulse rate (beats per minute) accurately measured by BabySat

Characteristic	Overall
Root Mean Square for Oxygen (percent)	
No. Obs.	35
Mean (SD)	2.16 (0.77)
Median	2.08
RMS for Pulse Rate (beats per minute)	
No. Obs.	35
Mean (SD)	3.53 (1.31)
Median	3.47



Clinically proven accuracy of BabySat across all skin tones and across all ankle circumferences.

Several factors have been shown to influence the accuracy of pulse oximetry. Recent evidence suggests that the accuracy of pulse oximetry differs in subjects of different skin pigmentations with decreased accuracy in patients with dark skin. To evaluate the accuracy of BabySat across all skin tones, a comparable analysis was carried out using BabySat and the Rad-97 Pulse Co-Oximeter. Similar comparative analysis using BabySat and the Rad-97 Pulse Co-Oximeter was carried out for ankle circumferences. Neither skin tone, nor ankle circumference had an effect on the bias thereby confirming the accuracy of BabySat comparable to the FDA-cleared Rad-97 Pulse Co-Oximeter.

Table 4: No significant difference in SpO2 and PR across skin tones[i]

	Fitzpatrick Category	
Characteristic	**Light (1-3)**	**Dark (4-6)**
Root Mean Square for Oxygen (percent)		
No. Obs	30	5
Mean (SD)	2.24 (0.79)	1.68 (0.45)
Median	2.10	1.51
Root Mean Square for Pulse Rate (beats per minute)		
No. Obs.	30	5
Mean (SD)	3.58 (1.33)	3.22 (1.25)
Median	3.65	3.05

Table 5: No significant difference in SpO2 and PR across ankle circumferences[i]

	Tertile		
Characteristic	**First**	**Second**	**Third**
RMS for Oxygen (percent)			
No. obs.	8.00	16.00	11.00
Mean (SD)	2.46 (1.10)	2.00 (0.67)	2.17 (0.63)
Median	2.20	1.71	2.11
RMS for Pulse Rate (beats per minute)			
No. obs.	8.00	16.00	11.00
Mean (SD)	4.18 (1.20)	3.18 (1.11)	3.58 (1.56)
Median	4.07	3.03	3.84

BabySat and Rad-97 Pulse Co-Oximeter have comparable readings through varying degrees of motion

Motion has been known to induce considerable error into pulse oximetry accuracy. To determine the influence of motion on BabySat readings, a comparative analysis of BabySat and Rad-97 Pulse Co-Oximeter was carried out throughout an array of typical active and passive infant activities such as sleeping, awake time, feeding, diaper changing, rocking etc. Motion was quantified in terms of the standard deviation of the accelerometer reading over each one-second period. This measure of motion is presented to the user as Movement Level and is expressed in units equivalent to 0.25 m/s^2. As expected, there was a significant difference in measured motion between infants that were asleep vs. awake (Figure 3). For Pulse Rate accuracy the mean ARMS for behaviors indicative of motion, (those other than asleep and still) were within the specific performance target of 10 beats/min (Figure 4.1). Behaviors not indicative of motion were within the performance target of 5 beats/minute. Additionally, mean ARMS for SpO2 across all behaviors were within the specific performance target of 3% (Figure 4.2). Motion resulted in somewhat increased values. The lack of statistical significance indicates that differences do not exist for sleep state or for activities (Figure 4.2). This is also apparent from the proximity of the means.

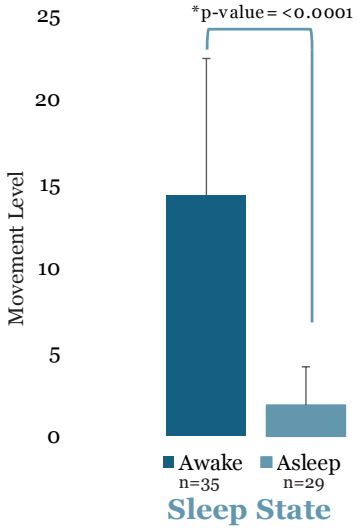


Figure 3: Significant difference in movement detected when sleeping vs awake (as expected). Error bars indicate standard deviation.

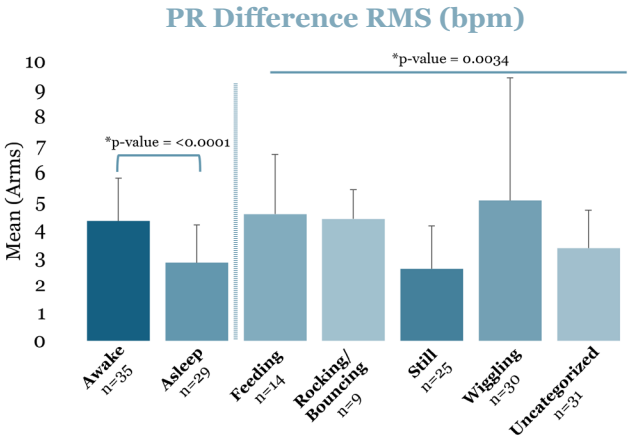


Figure 4.1: Pulse Rate accuracy was affected by movement, but stayed within acceptable bounds[i]. Error bars indicate standard deviation.

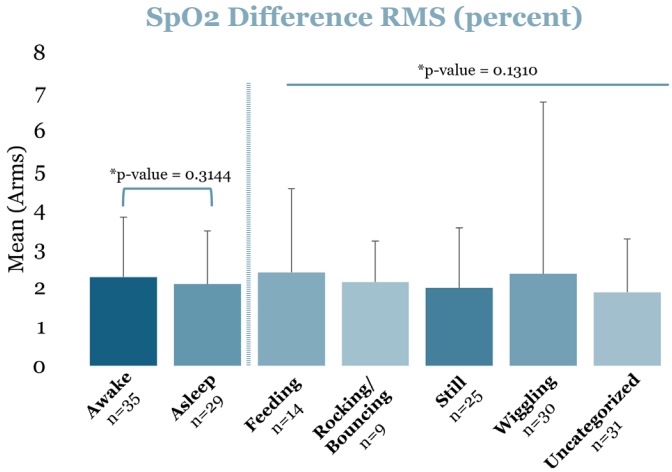


Figure 4.2: SpO2 accuracy not significantly affected by movement. Error bars indicate standard deviation.

[i]A one-way ANOVA showed that accuracy was not significantly different based on Fitzpatrick category (p=0.1374 for oxygen and p=0.5770 for pulse rate). A one-way ANOVA showed that accuracy was not significantly different across ankle circumferences (p=0.4080 for oxygen and p=0.2157 for pulse rate).

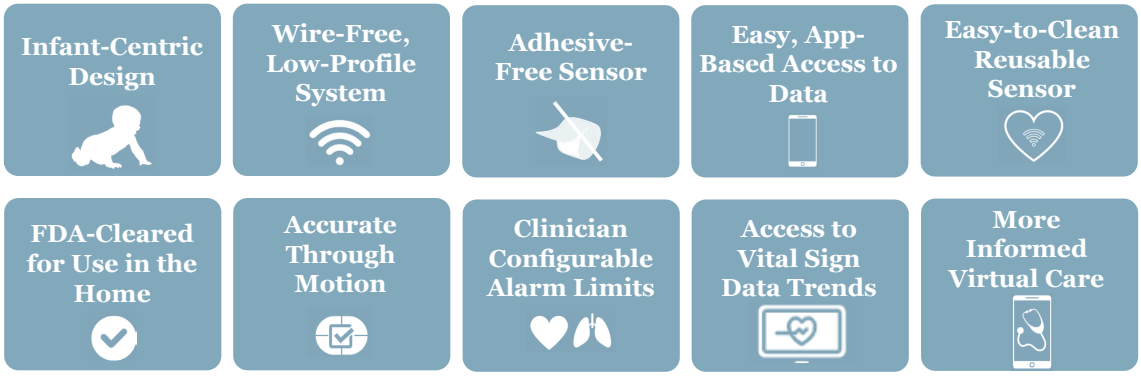


Figure 5: BabySat offers advanced features for easy at-home use

No adverse skin irritations were reported in association with BabySat

Four out of 35 subjects (11.4%) experienced skin irritation associated with contact with the Rad-97 Pulse Co-Oximeter sensor and adhesive. Subjects observed to have skin irritation ranged in age from 7 weeks to 10 months of age with a weight range of 9.5-23 lbs. No skin irritations were recorded in association with BabySat.

Conclusion

While the importance of continual home monitoring of vital signs in vulnerable neonates and infants has been demonstrated in several studies, the accuracy of these readings have been shown to be influenced by several factors such as skin pigmentation, motion and sensor placement. In a preclinical study carried out to ensure the accuracy and precision of pulse oximeter bias due to these factors, BabySat vital signs readings have been demonstrated to be comparable to the gold standard co-oximetry readings in healthy adults across the extremes of skin tone. To further evaluate the accuracy of BabySat vital sign readings, an at-home study was conducted to simultaneously compare readings of BabySat and the FDA-cleared Rad-97 Pulse Co-Oximeter. BabySat readings were also found to be comparable to Rad-97 Pulse Co-Oximeter readings in the at-home setting. Additionally, this study demonstrates clinically proven accuracy of BabySat across all skin tones and across the range of ankle circumferences observed in the relevant infant population where BabySat would be used. Most importantly, BabySat and Rad-97 Pulse Co-Oximeter have comparable readings through varying degrees of motion as measured during typical infant behaviors. Due to the infant-friendly, adhesive-free design of BabySat, no adverse events related to skin irritation were reported in association with BabySat.

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Owlet Baby Care, Inc.
(844) 334-5330
contact@owletcare.com
3300 N. Ashton Blvd, Suite 300
Lehi, UT 84043